

REMARKS**I. STATUS OF THE CLAIMS**

Claims 32-47 are pending in the present application. In the Office Action dated February 18, 2004, the Examiner rejected claims 32-47. By this Amendment, claims 32-35 and 43 are amended to further clarify the Applicant's invention. Support for the amendments presented herein can be found on page 8, lines 30-34 of the Applicant's specification. Furthermore, claims 37-40 are amended to correct a typographical error. Claims 41 and 47 are canceled. Applicant submits that no new matter is presented by these amendments.

II. CLAIM REJECTION UNDER 35 U.S.C. §112

In the Office Action dated February 18, 2004, the Examiner rejected claim 41 as being allegedly indefinite for failing to point out and distinctly claim the subject matter that the Applicant regards as the invention. By this Amendment, claim 41 has been canceled. Thus, Applicant respectfully requests withdrawal of this rejection.

III. CLAIM REJECTIONS UNDER 35 U.S.C. §103(A)

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992).

Second, the prior art can be modified or combined to reject claims as *prima facie* obvious only if there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800

F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Obviousness does not require absolute predictability; however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In Re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143 (CCPA 1976).

Finally, the prior art reference or combination of references must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All the words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Furthermore, if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP §2142.

A. Rejection of Claims 32-33 over Caburet in view of Hoffman

In the Office Action, claims 32-33 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 5,576,068 to *Caburet et al.* in view of U.S. Patent No. 4,656,083 to *Hoffman et al.* This rejection is respectfully traversed.

Caburet is directed to a method of treating a packaging element, especially a sealing element, including coating the element with a polymer film formed by cold-far-remote-plasma-assisted polymerization of particular siloxanes or silazanes (*Caburet*, Abstract, claim 1). The method of *Caburet* is used to provide an improved barrier between packaging materials and the goods contained therein (col. 2, line 35-39).

Hoffman is directed to a method of treating articles to improve their biocompatibility. Specifically, *Hoffman* is directed to the deposition of certain gases as biocompatible polymers on clean surfaces of substrate materials for use as tissue materials or other orthopedic implants (col. 4, lines 19-22).

Applicant has diligently searched the cited references and is unable to find any motivation to combine the reference teachings. *Caburet* relates to the coating of

packaging materials to improve the barrier between the packaging materials and the goods contained therein. *Hoffman* relates to treating articles to render them biocompatible. There simply is no reason why one of skill in the art would attempt to combine the reference teachings. It is unclear what motivation is believed to exist by the Examiner, since no motivation to combine the references was provided in the Office Action. Further, since there is no motivation to combine the reference teachings, there is also no reasonable expectation that combining the reference teachings would result in a successful combination.

Assuming, *arguendo*, that the references are properly combined, the combination of references fails to teach all elements of Applicant's claimed inventions as set forth in amended claims 32 and 33. Neither *Caburet* nor *Hoffman*, alone or in combination, teach the use of cold plasma polymerization to create a layer of one or more cold plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of an apparatus for dispensing a medicament, which surfaces come into contact with medicament during storage or dispensing, where the apparatus is selected from the group consisting of an inhaler, an inhaler housing, a nasal pump, a non-pressurized actuator, and a foil storage type. As such, the combination of *Caburet* and *Hoffman* is insufficient to support a rejection under 35 U.S.C. §103(a).

For at least the reasons presented above, the Examiner has failed to establish a *prima facie* case of obviousness with respect to the combination of *Caburet* and *Hoffman*. As such, Applicant respectfully requests withdrawal of this rejection.

B. Rejection of Claim 34 over Ashurst in view of Hatada

In the Office Action, claim 34 was rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 6,131,566 to *Ashurst et al.* in view of U.S. Patent No. 4,265,276 to *Hatada et al.* This rejection is respectfully traversed.

Ashurst is directed to a metered dose inhaler having part or all of its internal surfaces coated with one or more fluorocarbon polymers, optionally in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation comprising albuterol, or a physiologically acceptable salt thereof, and a fluorocarbon

propellant, optionally in combination with one or more other pharmacologically active agents or one or more excipients (col. 1, lines 66-67 to col. 2, lines 1-6).

Hatada is directed to a polyvinyl chloride tube having an inner surface that is crosslinked using cold plasma polymerization to reduce the diffusion, migration, and volatilization of additives that are blended with the polymeric material that forms the tube (col. 2, lines 1-21).

Applicant has reviewed the references in great detail and has found no motivation to combine the reference teachings. One of ordinary skill in the art would simply have no reason to modify a reference directed to a fluorocarbon polymer coated inhaler with a reference directed to a crosslinked PVC tube. Furthermore, the Examiner provided no such motivation, as is required to establish a *prima facie* case of obviousness. Given that there is no motivation to combine the reference teachings, there is likewise no reasonable expectation that combining the references would result in a successful combination.

Assuming, *arguendo*, that the references are properly combined, the combination of references fails to teach or disclose all elements of Applicant's invention as set forth in amended claim 34. Specifically, neither *Ashurst* nor *Hatada*, alone or in combination, teach use of cold plasma polymerization to create a layer of one or more cold plasma polymerized siloxane monomers bonded to at least a portion of one or more internal surfaces of an apparatus for dispensing a medicament, which surfaces come into contact with medicament during storage or dispensing, where the apparatus is a metering valve for use with a pressurized container. As such, the combination of *Ashurst* and *Hatada* is insufficient to support a rejection under 35 U.S.C. §103(a).

Accordingly, it is Applicant's position that a *prima facie* case has not been made with respect to the combination of *Ashurst* and *Hatada*. As such, Applicant respectfully requests withdrawal of this rejection.

C. Rejection of Claims 35-40 and 42-46 over Ashurst in view of Hatada and in further view of Chippendale

In the Office Action, claims 35-40 and 42-46 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 6,131,566 to *Ashurst et al.* in view of U.S. Patent No. 4,265,276 to *Hatada et al.* and in further view of U.S. Patent No. 5,349,944 to *Chippendale et al.* This rejection is respectfully traversed.

Each of claims 35-40 and 42-46 depend directly or indirectly from claim 32, claim 34, or both. For the reasons stated above, it is Applicant's position that the Examiner has failed to establish a *prima facie* case of obviousness with respect to claims 32 and 34. Accordingly, it is believed that the inventions set forth in claims 32 and 34 are novel and non-obvious, and therefore, the claims that depend from claims 32 and 34 are also novel and non-obvious.

D. Rejection of Claims 43-46 over Caburet in view of Hoffman, Ashurst, and Chippendale

In the Office Action, claims 43-46 were rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 5,576,068 to *Caburet* in view of U.S. Patent No. 4,656,083 to *Hoffman* in view of U.S. Patent No. 6,131,566 to *Ashurst et al.*, and in further view of U.S. Patent No. 5,349,944 to *Chippendale et al.* This rejection is respectfully traversed.

Each of claims 43-46 depends directly or indirectly from claim 32. For the reasons stated above, it is Applicant's position that the Examiner has failed to establish a *prima facie* case of obviousness with respect to claim 32. Accordingly, it is believed that the inventions set forth in claim 32 is novel and non-obvious, and therefore, the claims that depend from claim 32 are also novel and non-obvious.

E. Rejection of Claim 47 over Caburet in view of Hoffman

In the Office Action, claim 47 was rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 5,576,068 to *Caburet* in view of U.S. Patent

No. 4,656,083 to *Hoffman*. By this Amendment, claim 47 has been canceled. As such, Applicant respectfully requests withdrawal of this rejection.

IV. CONCLUSION

All of the amended claims and their associated dependent claims are believed allowable, for the reasons that no reference discloses, teaches, or suggests the steps or elements recited in each claim.

The foregoing is submitted as a full and complete response to the Office Action mailed February 18, 2004 and is believed to place all claims in the application in condition for allowance. Such action is courteously solicited.

If the Examiner believes that there are any issues that can be resolved by telephone conference, or if there are any informalities that may be addressed by an Examiner's amendment, please contact the undersigned at (404) 504-7728.

Respectfully submitted,



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CERTIFICATE OF FACSIMILE

The undersigned hereby certifies that on June 18, 2004 this document for Application Serial No. 10/047,986 was sent by facsimile to the attention of Examiner Darwin P. Erezo in Group Art Unit 3761 at facsimile number (703) 872-9306.

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